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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/339,818	06/25/1999	MARK E. DAVIS	038134-50010	3090

9629 7590 10/22/2002

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EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/22/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/339,818</b>	Applicant(s) <b>Davis t al.</b>	
	Examiner <b>L. E. Crane</b>	Group Art Unit <b>1623</b>	

**- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -**

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

## Status

- ☒ Responsive to communication(s) filed on **-05/02/02 (amdt F & 1.131 Declaration)-**.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claims **---1-3, 6-10, 18, 24-27, 30-34, 44 and 46---** are pending in the application. Claims **-[]-** have been cancelled.
- Of the above claim(s) **---[]---** is/are withdrawn from consideration.
- ☐ Claim(s) **---[]---** is/are allowed.
- ☒ Claims **---1-3, 6-10, 18, 24-27, 31-32, 44 and 46---** are rejected.
- ☒ Claims **---30 and 33-34---** are objected to.
- ☐ Claim(s) **---[]---** are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The proposed drawings, filed on **-05/02/02-** are ☒ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-[]-** is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119(a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-[]-**.
- ☐ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: **-[]-**.

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). **---[]---**
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☒ Interview Summary, PTO-413; PN's **12 & 13**
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other: **-[]-**

U.S. Patent Trademark Office

## Office Action Summary

PTO-326 (Rev. 06/19/01)

S. N. 09/339,818

Copy for ☒ **FILE** ☐ **APPLICANT**

Paper No. **23**

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No claims have been cancelled, claims 1, 24 and 25 have been amended, amendments to the disclosure except for one (see below) have been entered, and no claims have been cancelled as per the amendment filed May 2, 2002. A declaration under 37 C.F.R. §1.131 has been  
5 entered and considered during the preparation of the instant Office action.

Claims 1-3, 6-10, 18, 24-27, 30-34, 44 and 46 remain in the case.

The disclosure is objected to because of the following informalities:

10 Applicant is respectfully requested to delete the graphs found on pages 53, 57, 58, 59 and 60 from the specification in favor of formal drawings. See 37 C.F.R. §1.58(a).

15 Applicant's submission of replacement pages for pages 42, 44 and 48 is noted and is incorrect because of the use of the term "Figure" and the insertion of a "Description of Figures" into the specification. Reaction "Schemes" are not graphs and therefore do not need to be separated as "Figures." Applicant is encouraged to amend the disclosure by removal of the instant "Description of Figures" and to amend pages 42, 44 and 48 by replacement of the terms "Figure #" by the terms  
20 -- Scheme # -- with appropriate amendments to the disclosure to make references to the Schemes consistent as appropriate.

Appropriate correction is required.

Applicant's arguments filed May 2, 2002 have been fully considered but they are not persuasive.

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Applicant will note that the Figures newly submitted were approved by Drafting, and the "Brief Description of the Figures" has been entered. However, part of the amendment to the disclosure has not been entered as not being in proper form; e.g. the portions of the disclosure  
5 corresponding to the new figures have not been cancelled. Therefore, re-submission of the portion of the amendment, amended as requested, is respectfully requested.

Claims 1-3, 6-10, 18, 24-27, 30-34, 44 and 46 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter  
10 which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 1-3, 6-10, 18, 24-27, 30-34, 44 and 46 the generic terminology "co-monomer" and "cyclodextrin copolymer" implies a far  
15 wider scope of subject matter than applicant has enabled within the instant specific embodiments. Applicant is therefore respectfully requested to more nearly limit the scope of the instant claims to the scope of the enabled embodiments.

Applicant's arguments filed May 2, 2002 have been fully considered  
20 but they are not persuasive.

Examiner notes the amendment of claims 1, 24 and 25, but the limitation ("water-soluble") fails to further limit the instant subject matter to enabled subject matter because the new limitation describes what the compounds being claimed do, not what they are structurally.  
25 See Regents of the University of California v. Eli Lilly (119F.3d 1559 at 1568; 43 USPQ2d 1398 at 1406 (Fed. Cir 1997)) which MPEP §2163 at page 2100-162, column 1, quoted as follows: "A definition by function

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alone 'does not suffice' to describe a coding sequence 'because it is only an indication of what the gene does, rather than what it is.'"

Applicant argues that because the instant filed sworn declaration and evidence supplied therewith antedates the earliest filing date of the  
5 **Kosak et al. '736** reference, the instant grounds of rejection should be withdrawn. Examiner respectfully disagrees and refers applicant to examiner response following the art rejection below for the reason why the instant grounds of rejection have been maintained.

10 The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

15 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

20 (c) the invention was described in a patent granted on an application to another filed in the United States before the invention thereof by applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent."

25 The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

30 "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

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Claims 1-3, 7-10, 18, 24-27, 31-32, 44 and 46 are rejected under 35 U.S.C. §102(e) as being anticipated by, or alternatively under 35 U.S.C. §103(a) as being unpatentable over **Kosak '736** (PTO-1449 ref. **BE**).

5       The instant claims are directed to copolymers of cyclodextrins and various  $\alpha,\omega$ -diamino linkers optionally derivatized with biologically active ligands, methods of making, pharmaceutical compositions thereof, and a method of delivering pharmaceuticals therewith.

10       **Kosak '736** at column 15, line 30 through column 16, line 65 and column 20, line 63 through column 26 line 34 discloses copolymers of cyclodextrins and diamines, pharmaceutical compositions thereof, and the delivery of pharmaceuticals therewith which anticipate the instant noted claims because said instant claims do not specify the particular cyclodextrin/diamine co-polymers.

15       Alternatively, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to read the instant claims to include the cyclodextrin/diamine copolymers of the **Kosak '736** reference or to read said reference broadly to include all possible cyclodextrin/diamine co-polymers including those generically disclosed  
20       in step "a" of claim 1.

25       Therefore, the instant claimed cyclodextrin/diamine copolymers, methods of making, pharmaceutical compositions thereof, and methods of pharmaceutical delivery therewith were anticipated by the **Kosak '736**, or where not anticipated would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

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Applicant's arguments filed May 2, 2002 have been fully considered but they are not persuasive.

Examiner notes the amendment of claims 1, 24 and 25, but the limitation fails to avoid the prior art because the new limitation describes what the compounds being claimed do, not what they are structurally. See Regents of the University of California v. Eli Lilly (119F.3d 1559 at 1568; 43 USPQ2d 1398 at 1406 (Fed. Cir 1997)) which MPEP §2163 at page 2100-162, column 1, quoted as follows: "A definition by function alone 'does not suffice' to describe a coding sequence 'because it is only an indication of what the gene does, rather than what it is.'"

In addition, applicant has submitted a declaration filed under 37 C.F.R. § 1.131 signed by applicants Mssr. Davis and Mlle. Pun (nee Hwang) which alleges that the instant claims are based on research which antedates the earliest filing date of Kosak et al. '736 on the basis of an undated research report submitted by Mlle. Hwang (hereinafter "Hwang report") to the faculty of California Institute of Technology. Examiner has review the Hwang report, and finds that it supports applicant's allegations concerning applicant's specific embodiments, but does not extend to the subject matter of the Kosak et al. '736 reference. Therefore, while examiner does not question the allegation that the Hwang report does antedate the earliest Kosak et al. '736 filing date, examiner does not agree that the Hwang report covers subject matter beyond that of the instant enabled embodiments and for this reason has maintained the instant grounds of rejection. Examiner suggests that limitation of the instant claims to more nearly conform to the instant disclosed embodiments while avoiding the Kosak disclosure is one way applicant may chose to avoid the instant grounds of rejection.

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Claims 30 and 33-34 are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and/or amended to overcome rejections under 35 U.S.C. §112.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can



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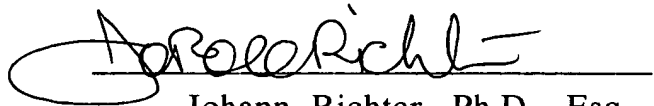
normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at (703)-308-4624.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

LECrane:lec

10 10/20/02



Johann Richter, Ph.D., Esq.  
Supervisory Patent Examiner  
Technology Center 1600